K070798

OCT 4 2007

Coeur, Inc.

Coeur Medical, a division of Coeur, Inc.
Adapters for CT and/or Angiographic Power Injectors

510(k) Summary

1. **Submitter:**

Name:	*Coeur Medical, a division of Coeur, Inc.*
Address:	*209 Creekside Drive*
	Washington, NC 27889
Phone:	*(615) 547-7923 (Corporate Office)*
Fax:	*(615) 547-7937 (Corporate Fax)*
Contact:	*Debra F. Manning, VP, Q & RA*
Date:	*October 2, 2007*

2. **Device:**

Trade/Proprietary Name:	*Coeur, Inc. Adapters for CT and/or Angiographic Power Injectors*
Common/Usual Name:	Adapter for Power Injectors
Classification Name:	Accessory, Injector and Syringe, Angiographic

3. **Legally Marketed Devices to which Substantial Equivalence is claimed:**

Coeur Front Load Injector Retrofit Kit (K965214) – Coeur

Front Load Injector Turret and 200ml Front Load Syringe (K960965) – Coeur

CT 8000 Digital Injection System (K912944) – Mallinckrodt Group, Inc.

Medrad Envision CT Injection System (K993728) – Medrad

Coeur Injector Adapter/Pressure Jacket (K032920) – Coeur

Medrad MCT, MCT Plus Injector/Medrad Front Load (K924116) - Medrad

4. **Device Description:**
As defined by 21 CFR 870.1650, an angiographic injector and syringe is a device that consists of a syringe and a high-pressure injector which are used to inject contrast material into the heart, great vessels, and coronary arteries to study the heart and vessels by x-ray photography. The Coeur adapter is a unit designed to install onto legally marketed power injectors to enable use of the Coeur syringe with such injectors. It includes a component that affixes to the ram of the power

injector to adapt it to fit the plunger of the Coeur syringe. It also includes a plastic lever component that allows the injector to be used more like the existing Mallinckrodt injector and will also be sold separately as a replacement part for that injector.

5. **Intended Use of Device:** The Coeur, Inc. Adapters are for use in adapting CT and/or Angiographic power injectors for use with Coeur syringes.

6. **Summary of Technological Characteristics As Compared to Predicate Devices:**

Technological Characteristics	Proposed Device	Coeur Devices	Medrad Devices	Mallinckrodt (LF) Device	Rationale for Applicable Differences
Intended Use	For use in adapting power injectors for use with Coeur syringes to enable the intended use of the power injectors (injection of contrast, saline, or other diagnostic fluids into a patient) to be accomplished using Coeur syringes.	Same	Syringe based fluid delivery systems for injecting contrast into patient.	Injects contrast into vascular system for angiographic or CT as prescribed.	NA – The proposed device does not alter the intended use (injecting contrast, saline, or other diagnostic fluid into patient) of the power injectors upon which it will be installed.
Sterile	No	No	No	No	NA – The disposable syringe is sterile, not the adapters/power injectors with which they are used.
Components	Combinations of steel and anodized aluminum, o-rings and plastic components including levers with magnets.	Steel and anodized aluminum and o-rings or plastic	Injector system includes hardware and software	Injector system including hardware and software	The proposed device incorporates a plastic lever to enable use of the syringe system similar to a feature available with some Mallinckrodt equipment. Otherwise, the differences are not applicable as the components are durable for their intended use.
Connection Method	Mechanically affixed to injector in a secure manner (i.e., affixed with bolts, screws, and/or dowel and roll pins.).	Same	NA	NA	NA
Function	Holds disposable syringe in position in front of injector ram.	Same	Same	Same	NA

If Substantial Equivalence was based on an Assessment of Performance Data, the following information is also provided:

1. **Non-clinical Tests Submitted:** *Verification of functional performance has been performed to ensure that the adapter can be properly installed, the syringe will properly load into the injector, and that the syringe can be filled and used to inject contrast, saline, or other diagnostic fluids into the patient without affecting the function of the power injectors.*

The installation, the loading, and the injection were all successfully completed. The equipment performed as intended.

2. **Clinical Tests Submitted:** *NA*

3. **Conclusions Drawn from Non-clinical and Clinical Tests Submitted:** *The primary difference between the proposed Coeur devices and the currently marketed Coeur devices is that the proposed device will be used upon injectors for which it is designed to fit – the form and function will not be significantly different. The proposed design will also allow components that may be used with other power injectors, including, for example, the incorporation of a lever that allows the system with the Coeur syringe to use a "Used Syringe Alarm" feature available with the Mallinckrodt system. The lever will also be available for sale separately as a replacement component. Coeur has expanded its business to include the offering of service for power injectors in its new service division and replacement components are needed for this division. This lever is one such replacement component.*

The primary difference between the proposed devices and legally marketed power injectors is that it works in conjunction with the power injectors without changing their intended use, to allow use of the Coeur syringes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Coeur Medical a division of Coeur, Inc.
c/o Ms. Debra F. Manning
Vice President, Quality & Regulatory Affairs
209 Creekside Drive
Washington, NC 27889

OCT 4 2007

Re: K070798
Trade/Device Name: Coeur, Inc. Adapters/Pressure Jackets for CT and/or Angiographic Power Injectors
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: August 31, 2007
Received: September 4, 2007

Dear Ms. Manning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070798

Device Name: Coeur, Inc. Adapters/Pressure Jackets for CT and/or Angiographic Power Injectors

Indications For Use:

for use in adapting CT and/or Angiographic power injectors for use with Coeur Syringes

Prescription Use _√_ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070798